REMARKS/ARGUMENTS

Claims 1-18, 20, 21 and 23-34 remain pending in the application, wherein no claims have been amended, added or cancelled by this amendment.

I. INTRODUCTION

The present application discloses soft tissue interference screws that are designed to provide fixation of a soft tissue graft against both cortical and cancellous bone tissue found within a bone tunnel. Interference screws generally work by pushing one or more strands of a soft tissue graft against the bone tunnel wall. In the short term, interference screw fixation needs to be strong enough to firmly hold the soft tissue graft in place and prevent pull-out or substantial loosening of the graft before the graft and bone have had a chance to heal and grow together. In the long run, it is advantageous for the soft tissue graft to fuse together with the bone tissue to form a permanent living tissue graft. Once substantial fusion of the soft tissue graft and bone tissue have occurred the interference screw becomes largely superfluous. *See* Declaration of Hugh S. West, Jr., M.D. ("West Decl."), ¶ 2.

One of the challenges of interference fixation is providing an interference screw that is able to exert sufficient force to provide strong initial fixation of the soft tissue graft, but not so much force that it causes long-term damage to, and potential weakening of, the soft tissue graft. The amount of force that is applied by an interference screw against a soft tissue graft is related to the diameter of the screw relative to the diameters of the bone tunnel and soft tissue graft, as well as the relative hardness of the bone. Because of variability in bone hardness among patients, as well as variability in the thickness of soft tissue strands between different persons, designing an interference screw that is able to strike the correct balance between providing strong initial fixation, on the one hand, and preventing undo damage to the soft tissue graft, on the other, is a specific challenge of interference screw design. *See* West Decl., ¶ 3. Accordingly, there is a need, long-felt in the art, to provide interference screws and methods able to provide strong initial fixation while also preventing undo damage to the soft tissue graft.

One proposed solution is to provide a pair of short interference screws that are placed at each end of the bone tunnel in order to provide bicortical fixation, *i.e.*, U.S. Patent No. 6,387,129 to Rieser et al. According to this method, an initial fixation force is applied by each interference screw in the hard cortical bone region at either end of the bone tunnel. One disadvantage of this fixation system is the practical difficulty in placing the fixation screw at the back of the bone

tunnel after first drawing the soft tissue graft through the bone tunnel (*i.e.*, the screw closest the joint must be placed deeply enough to firmly engage cortical bone but not so deeply as to extend beyond the bone tunnel and scrape against the cartilage of the joint or interfere with the passive motion of the joint). West Decl., ¶ 4.

The interference screws and methods disclosed in the present application have proven to be capable of striking the correct balance between strong initial fixation of the soft tissue graft while preventing undo damage to the soft tissue graft. The inventive interference screws provide strong initial fixation of the soft tissue graft by having a length sufficient to provide both cortical and cancellous bone fixation of the soft tissue graft. *See* West Decl., ¶ 5. Moreover, the increased diameter of the inventive interference screws in the cortical bone region of the bone tunnel provides even greater initial fixation of the soft tissue graft. Conversely, the reduced diameter of the inventive interference screws in the cancellous bone region of the bone tunnel prevents undo damage to the soft tissue graft by providing less force per unit length compared to the proximal threaded section. *See* West Decl., ¶ 6. According to one embodiment, the length of the interference screw is such that it extends through a majority of the bone tunnel. Because the cancellous bone region is much thicker than the cortical bone region, preferred interference screws provide less force per unit length along a majority of the interference screw in the larger, but softer, cancellous bone region, while limiting the strongest fixation to the smaller, but harder, cortical bone region.

II. RESPONSE TO CLAIM REJECTIONS

Applicant reincorporates by references the arguments set forth in Amendment "C" and Response, filed August 20, 2004. In addition, Applicant submits the Declaration of Hugh S. West, Jr., M.D. under 37 C.F.R. § 1.132 in further support of the patentability of the claims in the present application.

The only references cited against apparatus claims 1-18, 20-21, 23-24, 28-29 and 31-32 are U.S. Patent No. 2,382,019 to *Miller* and U.S. Patent No. 6,387,129 to *Rieser et al.* It is the opinion of Dr. West that *Miller*, which discloses a compound screw designed for being hammered into wood, teaches nothing about orthopedic surgery, let alone how to design an interference screw that would be suitable for use in fixing a soft tissue graft within a bone tunnel. Based on the apparent dimensions and features of the compound screw of *Miller* shown in the drawings, it is Dr. West's opinion that the compound screw of *Miller* would be not be suitable

for use in orthopedic surgery as an interference screw in securing a soft tissue graft within a bone tunnel absent significant modification. West Decl., ¶ 8. Because *Miller* admittedly fails to teach or suggest every limitation contained in the apparatus claims (*i.e.*, none of the claims were rejected as being anticipated by *Miller*), the Office Action combined *Miller* with *Rieser*. *Rieser* is the only reference cited against apparatus claims 1-18, 20-21, 23-24, 28-29, 31 and 32 having anything do with fixation of a soft tissue graft within a bone tunnel. West Decl., ¶ 9.

Rieser discloses interference screws and methods for bicortical fixation of a soft tissue graft within a bone tunnel. *Rieser*, col. 2, lines 16-24. Thus, whereas interference screws within the scope of the claims of the present application are designed so that a single interference screw can be used to secure a soft tissue graft within a bone tunnel, *Rieser* requires to use of two interference screws, a proximal screw positioned near the back of the bone tunnel nearest the joint and a distal screw positioned near the front of the bone tunnel furthest from the joint. *Rieser*, col. 5, lines 22; West Decl., ¶ 10. Although the use of two interference screws according to *Rieser* is significantly more complicated than using a single interference screw, one would expect the use of two interference screws according to *Rieser* to provide bicortical fixation to more securely attach a soft tissue graft within a bone tunnel during ACL repair surgery compared with a single interference screw within the scope of the claims of the present application that only contacts a single cortical bone surface. West Decl., ¶ 11. In fact, an objective, third-party study comparing the use of a pair of bi-cortical screws according to *Rieser* and

A. Comparative Study Between Claimed Interference Screws and Interference Screws According to Rieser

A comparative study conducted by a disinterested third party found that a single interference screw within the scope of the claims of the present application provided significantly greater initial fixation of a soft tissue graft than a pair of interference screws used in the manner disclosed in *Rieser* to provide bicortical fixation. The single interference was able to provide greater initial fixation of a soft tissue graft even though the combined length of the two interference screws used to provide bicortical fixation was greater than the length of the single interference screw within the scope of the claims of the present application. West Decl., ¶ 12. The comparative study, which was authored by H.C. Chang et al., is entitled "Biomechanical Testing of Tibialis Anterior Graft Tibial Tunnel Fixation with Bioabsorbable RetroScrews and BioScrew XtraLok in Porcine Bones" (hereinafter "Chang Study"). West Decl., ¶ 13.

The Chang Study was carried out by Haw Chong Chang, MBBS, FRCSEd (Orth); John Nyland, Ed.D., P.T., S.C.S., A.T.C.; Akbar Nawab, MD; Robert Borden, MEng, EIT; and David N.M. Caborn, MD under the auspices of the Division of Sports Medicine, Department of Orthopedic Surgery, of the University of Louisville, which is located in Louisville, Kentucky. Exh. A, Chang Study, p. 1. To the best of Dr. West's knowledge and belief, neither Dr. West nor Linvatec Corporation ("Linvatec"), a licensee of the technology described and claimed in the present application, authorized, funded or otherwise had any interest in the Chang Study. West Decl., ¶ 14.

The stated purpose of the study was to "evaluate[] the failure mode, maximum load at failure, displacement at failure, and stiffness differences of doubled tibialis anterior graft-tibial tunnel fixation using retrograde bioabsorbable interference screws" sold by Arthrex, Inc. ("Arthrex") (the Assignee of *Rieser*) and a "35-mm BioScrew XtraLok" interference screw sold by Linvatec "after cyclical loading". West Decl., ¶ 15.

The 35-mm BioScrew XtraLok interference screw that was tested in the Chang Study falls within the scope of each of the independent apparatus claims, and also within the scope of some or all of the dependent apparatus claims, of the present application. West Decl., ¶ 16. The "Retrograde" screws used in the Chang Study, also referred to as the "RetroScrews" (Exh. A, Chang Study, pp. 1-2), as well as how they were used in the Chang Study, appear to fall within the scope of the claims of *Rieser*. It is therefore Dr. West's opinion that the Chang Study represents a direct comparison between the interference screws and the bicortical fixation method claimed in *Rieser* and the interference screw claimed in the present application. West Decl., ¶ 17.

The hypothesis of the Chang Study (later proved to be incorrect) was that "[t]here is no difference in maximum load, displacement and stiffness at failure of doubled tibialis interior graft-intibial tunnel fixation using [the] Retrograde [interference screws of Arthrex] and [the] 35-mm BioScrew XtraLok [interference screw of Linvatec] after cyclical loading." West Decl., ¶ 18.

The methods used in the Chang Study included "[t]welve specimens of porcine tibias [that] were divided into 6 matched pairs based on bone mineral densitometry. Wilcoxon tests comparisons were used to assess group differences ($P < .05$)." West Decl., ¶ 19.

The results of the Chang Study were as follows: "[m]aximum load at failure after cyclic loading for the RetroScrew was 778.7 ± 177.5 N, with a displacement of 5.3 ± 2 mm and a

stiffness modulus of 204.3 ± 52.9 N/mm. Maximum load at failure after cyclic loading for the BioScrew XtraLok screw was 1436.3 ± 331.3 N, with a displacement of 5.9 ± 2.6 mm and a stiffness modulus of 323.6 ± 56.8 N/mm." West Decl., ¶ 20. The Chang Study further stated the following: "[f]ixation using XtraLok screws displayed greater maximum load at failure than RetroScrew fixation (P = .028) as well as greater stiffness (P = 0.046). Significant differences were not evident for displacement at final pullout. All contstructs failed by graft pullout." West Decl., ¶ 21. Finally, the Chang Study concluded that "[f]ixation using a single 35-mm BioScrew XtraLok screw displayed increased maximum load at failure and stiffness compared with the 20-mm RetroScrew with 17-mm cortical backup fixation". In other words, a single 35 mm interference screw according to claims of the present application "displayed increased maximum load at failure and stiffness" compared to two interference screws according to *Rieser* having a combined length of 37 mm.

In Dr. West's opinion, as set forth in his declaration submitted herewith, the ability of a single interference screw to provide better initial fixation of a soft tissue graft than a pair of interference screws that not only provide bicortical fixation but have a greater combined length is a surprising and unexpected result that underscores and distinguishes the mechanical advantages of the claimed interference screw design. West Decl., ¶ 22.

B. Objective Evidence of Economic Success of the Claimed Interference Screws

In addition to the Chang Study objectively showing the superiority of the BioScrew XtraLok interference screw compared to the Retrograde interference screws (RetroScrew) of *Rieser*, sales for the BioScrew XtraLok interference screw have steadily increased since it was first introduced into the market in 2003. According to the sales figures contained in Exhibit C to the West Decl., sales for the BioScrew XtraLok interference screw increased from $88,761.98 in Quarter 3 of 2003 to $94,824.44 in Quarter 4 of 2004, and then to $143,254.92 in Quarter 1 of 2004. West Decl., ¶ 23.

To the best of Dr. West's knowledge and belief, sales for the BioScrew XtraLok interference screw are significantly higher than sales for the RetroScrews of Arthrex (*i.e.*, *Rieser*), even though *Rieser* was filed before the present application. In fact, to the best of Dr. West's knowledge and belief, the RetroScrews of Arthrex (*i.e.*, *Rieser*) have had, to date, little acceptance in the market. Thus, not only has an interference screw within with scope of the claims of the present application had good success in the market, its success and acceptance by

orthopedic surgeons appears to be significantly greater than interference screws within the scope of *Rieser*. West Decl., ¶ 24.

C. Conclusions Based on Objective Evidence

The Chang Study and the acceptance and market penetration of an interference screw within the scope of the claims of the present application are objective evidence of the inventiveness of the claimed interference screws of the present application over the cited art. *See* West Decl., ¶ 25. More particularly, the surprising and unexpected result of a single interference screw within the scope of the claims of the present application being able to provide significantly greater fixation compared to two interference screws that provide bicortical fixation and that have a greater combined length is objective evidence of the inventiveness of the claimed interference screws of the present application, as well as of the claimed methods, relative to the cited art. *See* West Decl., ¶ 26. Similarly, the evidence of economic success is further objective evidence of the inventiveness of both the apparatus and method claims of the present application. *See* West Decl., ¶ 27.

III. CONCLUSION

In view of the foregoing, Applicant believes that the claims are presently in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application, may be clarified through a telephone interview or that can be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 9th day of September 2004.

Respectfully submitted,

JOHN M. GUYNN
Registration No. 36,153
Attorneys for Applicant
Customer No. 022913

JMG:mla

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